UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. MYLAN TECHNOLOGIES INC., Defendant.	)	Case No. 2:22-cv-00216

OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT
(Doc. 64)

Defendant Mylan Technologies Inc. ("Mylan") requests partial summary judgment for its breach of contract counterclaim, as well as summary judgment declaring non-infringement of U.S. Patent Nos. 8,246,979 (the "'979 Patent") and 8,246,980 (the "'980 Patent"). Plaintiffs UCB, Inc., UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively, "UCB") oppose the motion or, in the alternative, request continued discovery under Fed. R. Civ. P. 56(d) on facts essential to their opposition.[1]

UCB is represented by Brian Bieluch, Esq., George F. Pappas, Esq., Jay I. Alexander, Esq., Jeffrey B. Elikan, Esq., Kendall A. Hoechst, Esq., Kevin B. Collins, Esq., Michael E. Bowlus, Esq., Nicholas L. Evoy, Esq., Richard L. Rainey, Esq., Ritchie E. Berger, Esq., and Thomas J. Sullivan, Esq. Mylan is represented by Christopher W.

[1] Rule 56(d) provides that when "a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may" defer consideration of the motion, deny the motion, allow time to obtain affidavits or declarations or take discovery, or issue any other appropriate order. By affidavit or declaration, the nonmovant must describe: "(1) what facts are sought and how they are to be obtained; (2) how these facts are reasonably expected to raise a genuine issue of material fact; (3) what efforts the affiant has made to obtain them; and (4) why the affiant's efforts were unsuccessful." *Gualandi v. Adams*, 385 F.3d 236, 244 (2d Cir. 2004) (interpreting prior version of rule). UCB, however, has not filed an affidavit or declaration in support of its Rule 56(d) request, so it is DENIED.

West, Esq., Deepro R. Mukerjee, Esq., Eric T. Werlinger, Esq., Jillian M. Schurr, Esq., Jitendra Malik, Esq., Joseph M. Janusz, Esq., Lance A. Soderstrom, Esq., Michael F. Hanley, Esq., Paul J. Perkins, Esq., and Timothy H. Gray, Esq.

I. Whether to Consider UCB's Additional Facts.

UCB's Response to Mylan's Statement of Undisputed Material Facts ("SUMF") both responds to Mylan's SUMF and contains additional facts which UCB contends are disputed. (Doc. 77-12.) UCB also submitted a separate Statement of Disputed Material Facts ("SDMF") in support of its opposition. (Doc. 77-11.)[2] "[T]he Local Rules do not provide an opportunity for the nonmoving party to file a statement of undisputed facts at the summary judgment stage." *Rotman v. Progressive Ins. Co.*, 955 F. Supp. 2d 272, 276 (D. Vt. 2013); *see also Schroeder v. Makita Corp.*, 2006 WL 335680, at *3-4 (D. Vt. Feb. 13, 2006) (same).

Generally, the court "disregard[s] [p]laintiff's additional facts unless it is clear from the parties' briefing that those facts are both material and undisputed." *Rotman*, 955 F. Supp. 2d at 276; *see also Boule v. Pike Indus., Inc.*, 2013 WL 711937, at *1-2 (D. Vt. Feb. 27, 2013) (same). However, Mylan has not moved to strike UCB's SUMF Response or SDMF, nor responded to UCB's SDMF. In resolving the pending motion, the court will therefore consider the additional facts to the extent they are undisputed or to the extent they identify a genuine issue of material fact.

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[2] In support of its partial motion, Mylan submits fifty-two paragraphs of facts supported by hundreds of pages of documents. In response, UCB responds to that statement and submits a separate statement of facts consisting of 112 paragraphs and hundreds of pages of supporting documents. This is not a briefing style that advances the goals of Fed. R. Civ. P. 1. *See* Fed. R. Civ. P. 1 (directing that the Federal Rules of Civil Procedure "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding"); *see also Allen v. Dairy Farmers of Am., Inc.*, 2014 WL 2610613, at *3 (D. Vt. June 11, 2014) ("In light of the voluminous factual record before the court, and the absence of any discernible effort by the parties to narrow the factual or legal issues before the court, the court will not attempt to set forth all of the undisputed facts but will instead only consider those facts necessary to address the issues of law raised by Defendants' motion.").

II. Undisputed Facts.

In May 2007, UCB received U.S. Food and Drug Administration ("FDA") approval for Neupro®, "a transdermal patch containing rotigotine in small microreservoirs dispersed in an adhesive matrix[,]" (Doc. 77-10 at 7), prescribed to treat Parkinson's disease and restless leg syndrome. It is comprised of "a backing layer and a self-adhesive matrix" with "a multitude of microreservoirs within the matrix, said microreservoirs containing rotigotine free base," "wherein all the microreservoirs have a maximum diameter that is less than the thickness of the matrix[.]" (Doc. 77-3 at 17.) The FDA approved a new formulation of Neupro® in April 2012 with additional indications after manufacturing changes and additional clinical trials. Neupro® has six patents associated with it in the FDA's Orange Book, including the four patents at issue in this case.

On December 16, 2016, Mylan filed Abbreviated New Drug Application No. 209982 (the "ANDA"), seeking FDA approval of a generic version of Neupro® (the "ANDA Products") and including a Paragraph IV certification to the '979 and '980 Patents.

Thereafter, on February 27, 2017, Mylan provided UCB notice of its Paragraph IV certification to the FDA that its ANDA Products would not infringe any valid claim of UCB's then-listed Neupro® patents (the "Notice Letter").[3] UCB states that "Mylan failed to identify any substantive grounds for non-infringement of the '979 and '980 Patents with respect to its Old Product, with the sole exception of claim 6 of the '979 Patent." (Doc. 77-11 at 10, ¶ 31.)

On March 24, 2017, UCB filed a complaint (the "2017 Complaint") in the District

[3] A generic drug manufacturer must certify to the FDA under one of four paragraphs for an Orange Book-listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). In a Paragraph IV certification, the company must include "a full and detailed explanation of why [each] claim is not infringed[]" or is invalid or unenforceable. 21 C.F.R. § 314.95(c)(7)(i). "Filing a paragraph IV certification means provoking litigation[]" because "[t]he patent statute treats such a filing as itself an act of infringement, which gives the brand [company] an immediate right to sue." *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012).

of Delaware alleging that Mylan's ANDA and ANDA Products infringed five patents, including the '979 and '980 Patents (the "2017 Action").[4] The '980 and '979 Patents expire on November 27, 2025 and September 1, 2027, respectively.

In its 2017 Complaint, UCB alleged in Counts III and IV:

> 50. Defendants have infringed the '979 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '979 Patent. In the Notice Letter, Mylan has not asserted non-infringement of claims 1-5 or claims 7-18 of the '979 Patent.
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> . . .
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> 57. Defendants have infringed the '980 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '980 Patent. In the Notice Letter, [Mylan] has not asserted non-infringement of claim 17 of the '980 Patent.

UCB, Inc. v. Mylan Techs., Inc., No. 2:19-cv-00148 (D. Vt. Mar. 24, 2017), ECF No. 1 at 13, 15 ¶¶ 50, 57. UCB alleged that Mylan's ANDA Products "would directly infringe" the '979 and '980 Patents, and "upon FDA approval of ANDA No. 209982, Mylan . . . will thereby infringe . . . one of more claims of the" '979 and '980 Patents. *Id.* at ¶¶ 51, 58. In the course of discovery in the 2017 Action, Mylan provided UCB with its ANDA.

The FDA issued a complete response letter on October 27, 2017, after "determin[ing] that [it] [could not] approve this ANDA in its present form." (Doc. 77-28 at 3.) The FDA noted that "the deficiencies have been classified as MAJOR[]" and any resubmission would constitute a "MAJOR AMENDMENT[.]" *Id.* at 9 (bolding omitted). The FDA set a one-year deadline for Mylan to respond. Mylan requested a one-year extension in 2018 to complete its resubmission "due to the complexity of the work required to fully address the [FDA's] drug product and process quality

[4] Because UCB filed an action within forty-five days of receiving notice of Mylan's Paragraph IV certification, Mylan's ANDA was subject to a thirty-month stay of approval by the FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 407 (noting that after a brand manufacturer files an infringement suit, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed").

comments . . . which pertain to drug product physical test acceptance criteria and drug product manufacturing process parameters." (Doc. 77-37 at 2.) Mylan sought and received subsequent extensions in 2019, 2020, and 2021.

On May 23, 2018, UCB submitted an Identification of Asserted Patents and Accused Products in the 2017 Action and did not mention the '979 or '980 Patents therein. It filed its Initial Infringement Contentions on May 30, 2018, and similarly omitted the '979 and '980 Patents. On August 21, 2018, Mylan provided UCB "a sample consent judgment that was entered in a different matter involving Mylan[]" and asked "if this would be acceptable for dealing with the . . . patents in the case that Plaintiffs are not asserting[,]" (Doc. 77-42 at 16), to which UCB replied on September 7, 2018 that discussion of a consent judgment was "premature[.]" *Id.* at 11.

On July 16, 2019, UCB filed an infringement action in the District of Vermont concerning two other patents connected with Neupro®: U.S. Patent Nos. 10,130,589 (the "'589 Patent") and 10,350,174 (the "'174 Patent"). *UCB, Inc. v. Mylan Techs., Inc.*, No. 2:19-cv-00128 (D. Vt. July 16, 2019), ECF No. 1 (the "2019 Action"). The '589 and '174 Patents were issued on November 20, 2018, and July 16, 2019, respectively, listed in the Orange Book, and will expire on December 22, 2030. Mylan filed a Paragraph IV certification for these patents and on July 29, 2019, sent notice of its submission to UCB.

The 2017 Action was transferred to the District of Vermont on August 26, 2019. In January 2020, Mylan asked UCB whether it would "make sense to revisit our discussions about potentially streamlining the [2017 Action.]" (Doc. 64-17 at 11.) On March 11, 2020, at UCB's request, Mylan provided UCB a draft Covenant Not to Sue (the "Covenant") regarding the '979 and '980 Patents, as well U.S. Patent Nos. 8,617,591 (the "'591 Patent") and 9,925,150 (the "'150 Patent") (collectively, the "Covenant Patents"). The Covenant pertained to "the drug products described in the Mylan ANDA, including any amendments and/or supplements thereto[.]" (Doc. 77-39 at 2.)[5]

[5] The Covenant refers to "the drug products described in the Mylan ANDA ('Mylan ANDA Products')[.]" (Doc. 77-49 at 2, ¶ 2.) UCB uses the terms "Old Product" and "New Product[.]" (Doc. 77-10 at 18.) Mylan uses both "ANDA product" and "ANDA products" in its motion,

On April 6, 2020, UCB proposed numerous edits to the Covenant. In the introductory section, it "changed the nature of the proposed covenant from a contract to a unilateral license offered to Mylan." Doc. 77-12 at 15; *see* Doc. 77-54 at 2 (changing "[t]his covenant . . . is by and between UCB . . . and Mylan[,]" to "[t]his covenant . . . is made by UCB . . . to Mylan" and "the Parties hereby covenant[,]" to "the Plaintiffs hereby covenant"). It also "eliminated Mylan's broad definition of 'the Mylan ANDA,' and specified that [it] refers to the ANDA 'as of March 16, 2020.'" (Doc. 77-12 at 15.) UCB removed the phrase "any amendments and/or supplements thereto[]" in the second paragraph ("Paragraph 2") and substituted "the drug products described in the Mylan ANDA ('Mylan ANDA Products')." (Doc. 77-54 at 2, ¶ 2.) It changed "Plaintiffs agree to and do release and discharge" Mylan from liability for infringement, to "Plaintiffs agree to and do covenant not to sue or otherwise hold liable" Mylan for infringement. *Id.*

UCB added a third paragraph ("Paragraph 3") to the Covenant, which it claims "limited the scope of Mylan's license to cover only the Old ANDA Product and those variations that do not 'alter the infringement analysis' with respect to any claim of the Covenant Patents." (Doc. 77-12 at 15.) UCB noted that this new paragraph purportedly "clarif[ied] that Mylan's license would extend only to Mylan's Old ANDA Product and certain variations thereof, with the scope of permitted variations defined and limited by the claims of the Covenant Patents." *Id.*

On April 17, 2020, Mylan rejected UCB's proposed Paragraph 3 and redrafted the Covenant to include "drug products described in the Mylan ANDA, including any amendments and/or supplements thereto[.]" (Doc. 77-55 at 2.)

After the parties negotiated the Covenant, on May 11, 2020, UCB advised Mylan:

> Mylan's last markup is not acceptable to our clients, and we do not here provide another turn of the documents because we've gone [back] and forth on this a number of times now, and because our points of disagreement are few but fundamental. . . . Mylan's continued insistence in striking language that appropriately limits the covenant to the ANDA and generic product of

(Doc. 64-12 at 25), but references an "originally submitted product" and a "newly proposed product" in its FDA submission. (Doc. 77-32 at 8.) The court follows the Covenant's language and adopts "ANDA Products" to refer to Mylan's generic version of Neupro®.

> which Plaintiffs are on notice (e.g., what was formerly Paragraph 3) is and will remain unacceptable to our clients. If this means that we are at an impasse, then those are the circumstances.

(Doc. 77-46 at 2.) In essence, UCB offered its version of the Covenant to Mylan on a take-it-or-leave-it basis. Thereafter, Mylan declined to sign UCB's version of the Covenant.

On June 16, 2020, UCB unilaterally executed and issued the Covenant "in substantially the same form as the[ir] April 6, 2020 draft[.]" (Doc. 77-10 at 14.) The final version of the Covenant states:

1. UCB Pharma GmbH represents that it possesses all right, title, and interest in and to the '979, '980, and '591 patents. UCB Pharma GmbH and LTS represent that they are the assignees of the '150 patent. This Covenant is conditioned upon Mylan possessing all right, title, and interest in and to [ANDA] No. 209982, describing a rotigotine transdermal system, including 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours ("the Mylan ANDA"), as of May 27, 2020.
2. Based on the foregoing representations and subject to the conditions set forth herein, Plaintiffs agree to and do covenant not to sue or otherwise hold liable Mylan, its parents, subsidiaries, affiliates, distributors, manufacturing or supply partners, marketing partners, customers, licensees, transferees, assignees, or successor companies for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA ("Mylan ANDA Products") infringes any claim of the '979, '980, '591, or '150 patents.
3. The Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020, provided, however, to the extent that Mylan thereafter – (1) amends, supplements or otherwise alters the Mylan ANDA so as to change any indication(s) sought therein, or (2) modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 patents – this Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture.
4. For the avoidance of any doubt, this Covenant does not expressly, or by

implication, estoppel, or otherwise, constitute an admission by Plaintiffs as to the scope or interpretation of, the infringement of, the validity of, or the enforceability of, the '979, '980, '591, or '150 patents, or of any other patent, including by not limited to U.S. Patent Nos. 10,130,589 and 10,350,174.

5. For the further avoidance of doubt, this Covenant applies only to products made and/or marketed under the Mylan ANDA as defined herein.

(Doc. 77-49 at 2-3, ¶¶ 1-5.)

The parties to the 2017 Action jointly filed a Stipulation and Order for Dismissal on July 17, 2020, agreeing that the dismissal was "without prejudice to Plaintiffs' ability to assert the Covenant Patents for any other ANDA or as provided in the Covenant." *UCB, Inc. v. Mylan Techs., Inc.*, No. 2:19-cv-00148 (D. Vt. July 17, 2020), ECF No. 96 at 1, ¶ 1. On July 20, 2020, the court issued the Stipulated Order and terminated the 2017 Action. This followed a May 13, 2020 Stipulation and Order, in which Mylan agreed not to contest infringement allegations of "Claims 1-3, 4, 7, and 10-12 of the '589 patent and Claims 1, 2, 5-6 and 14-15 of the '174 patent." *UCB, Inc. v. Mylan Techs., Inc.*, No. 2:19-cv-00128 (D. Vt. May 13, 2020), ECF No. 98 at 2, ¶ 1.

By Opinion and Order dated March 26, 2021, the District of Delaware invalidated certain claims of the '589 Patent. *UCB, Inc. v. Actavis Lab'ys UT, Inc.*, 2021 WL 1880993, at *25 (D. Del. Mar. 26, 2021), *aff'd*, 65 F.4th 679 (Fed. Cir. 2023).

On October 27, 2022, Mylan submitted an amendment to its ANDA to the FDA in response to the FDA's finding that Mylan's ANDA was inadequate. Mylan conducted a supplemental bioequivalence study that demonstrated that the ANDA Products remained bioequivalent to Neupro® after certain changes were made. Mylan also made changes to manufacturing and packaging. The FDA deemed Mylan's amendment a "major amendment." (Doc. 77-29 at 2.) Mylan sent UCB a notice of its ANDA and Paragraph IV certification, asserting there could be no infringement claim under the Covenant because its changes to the ANDA Products do not "alter the infringement analysis[,]" which "remains the same" for the Covenant Patents. (Doc. 64-19 at 11) (internal quotation marks omitted).

UCB filed this suit on December 12, 2022, seeking, among other things, a declaratory judgment that Mylan had infringed the Covenant Patents by pursuing its ANDA, "amendments[]," and ANDA Products. In addition, UCB requested an injunction preventing Mylan from further infringement. (Doc. 1.) UCB claimed that Mylan had "infringed at least claims 1-18 of the '979 Patent" and "at least claim 17 of the '980 Patent[.]" (Doc. 1 at 15, 19, ¶¶ 59, 80.) By filing an action on the '979 and '980 Patents within forty-five days of Mylan's October 27, 2022 notice letter, UCB obtained another thirty-month FDA stay of approval of Mylan's ANDA.

Mylan filed its Answer and Counterclaim on February 13, 2023. (Doc. 17.) It has amended the same to assert an affirmative defense of inequitable conduct based on alleged material omissions regarding the '589 and '174 Patents made by "the named inventors, including at least Dr. Arth, UCB, its predecessors, and/or their representatives" with an intent to deceive the U.S. Patent and Trademark Office. (Doc. 132 at 34.)

On May 9, 2023, UCB served its Initial Infringement Contentions on Mylan, asserting claims 1-2 and 4-18 of the '979 Patent and claim 17 of the '980 Patent and citing portions of Mylan's "original ANDA documentation[.]" (Doc. 77-12 at 28, ¶ 52) (emphasis omitted). With respect to these claims, UCB asserts that "Mylan's changes . . . are substantial and alter the infringement analysis with respect to at least this claim, and render Mylan's Reformulated ANDA Products not essentially the same as Mylan's Original ANDA Products." *Id.* at 29, ¶ 52.

Thereafter, on June 16, 2023, Mylan served its supplemental response to UCB's interrogatories. UCB states that this response "does not offer any basis for disputing infringement of 1–2, 4–5, and 7–18 of the '979 Patent and claim 17 of the '980 Patent, other than based on the arguments relating to the Covenant[,]" except for claim 6 of the '979 Patent. (Doc. 77-11 at 26, ¶ 97.)

On June 21, 2023, Mylan moved for partial summary judgment arguing UCB breached the Covenant in filing this action and seeking a declaratory judgment that it has not infringed the '979 and '980 Patents. (Doc. 64.) UCB opposed Mylan's motion for partial summary judgment on July 28, 2023, (Doc. 77), and Mylan replied on August 18,

2023. (Doc. 86.) On October 12, 2023, the court held oral argument, at which time it took the pending motion under advisement.

No court or tribunal has performed an infringement analysis or entered a judgment regarding infringement for the '979 or '980 Patents with respect to Mylan's ANDA Products.

III. Conclusions of Law and Analysis.

A. Standard of Review.

The court must grant summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is 'material' . . . if it 'might affect the outcome of the suit under the governing law.'" *Rodriguez v. Vill. Green Realty, Inc.*, 788 F.3d 31, 39 (2d Cir. 2015) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "A dispute of fact is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Id.* at 39-40 (quoting *Anderson*, 477 U.S. at 248). The court "construe[s] the evidence in the light most favorable to the non-moving party" and "resolve[s] all ambiguities and draw[s] all permissible factual inferences in favor of the party against whom summary judgment is sought." *Lenzi v. Systemax, Inc.*, 944 F.3d 97, 107 (2d Cir. 2019) (internal quotation marks omitted).

The moving party always "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). "Once the moving party demonstrates that there are no genuine issues of material fact, the nonmoving party must come forth with evidence sufficient to allow a reasonable jury to find in [its] favor." *Spinelli v. City of New York*, 579 F.3d 160, 166 (2d Cir. 2009) (alteration in original) (internal quotation marks omitted). "Thus, a nonmoving party can defeat a summary judgment motion only by coming forward with evidence that would be sufficient, if all reasonable inferences were drawn in [its] favor, to establish the

existence of [an] element at trial." *Id.* at 166-67 (alterations in original) (internal quotation marks omitted).

"The function of the district court in considering the motion for summary judgment is not to resolve disputed questions of fact but only to determine whether, as to any material issue, a genuine factual dispute exists." *Kaytor v. Elec. Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010) (citation omitted). "A non-moving party cannot avoid summary judgment simply by asserting a 'metaphysical doubt as to the material facts.'" *Woodman v. WWOR-TV, Inc.*, 411 F.3d 69, 75 (2d Cir. 2005) (quoting *Matsushita*, 475 U.S. at 586). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted). However, if the evidence "presents a sufficient disagreement to require submission to a jury[,]" the court should deny summary judgment. *Id.* at 251-52. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Kaytor*, 609 F.3d at 545 (internal quotation marks and emphasis omitted).

B. Whether Vermont Law Applies.

Mylan argues that UCB breached Paragraph 2 of the Covenant by filing this lawsuit alleging infringement of the '979 and '980 Patents. The Covenant does not include a choice of law provision although both parties rely on Vermont law in their briefs.

"Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humans., Inc.,* 518 U.S. 415, 427 (1996). To determine which state substantive law applies, "a federal court exercising diversity jurisdiction must apply the choice-of-law rules of the state in which that court sits to determine the rules of decision that would apply if the suit were brought in state court." *Liberty Synergistics Inc. v. Microflo Ltd.*, 718 F.3d 138, 151 (2d Cir. 2013). Because the court is sitting in diversity and the Covenant was signed in connection with a District of Vermont action by the parties to that action, the court agrees for the purposes

of this Opinion and Order that Vermont law governs Mylan's breach of the Covenant counterclaim.

"To state a breach of contract claim under Vermont law, Plaintiff must plead (1) the existence of a contract, (2) breach of the contract, and (3) damages." *Mooers v. Middlebury Coll.*, 2021 WL 4225659, at *5 (D. Vt. Sept. 16, 2021) (citing *Lapoint v. Dumont Constr. Co.*, 258 A.2d 570, 571 (Vt. 1969)). "A unilateral contract will form where an offeror makes an offer that can be accepted by performance, and the offeree performs." *Sutton v. Vermont Reg'l Ctr.*, 2019 VT 71A, ¶ 60, 212 Vt. 612, 642, 238 A.3d 608, 631 (citation omitted). The parties agree that the Covenant is an enforceable contract although Mylan did not sign it.[6] Mylan's agreement to the Stipulation and Order for Dismissal based on the Covenant suffices to establish a meeting of the minds that the Covenant would be binding upon the parties thereto. *See Bachli v. Holt*, 200 A.2d 263, 267 (Vt. 1964) ("An acceptance of a proposal may be accomplished by conduct as effective as though done verbally where it appears the acts of the parties conform to the terms proposed.") (citation omitted).

C. Whether the Covenant is Ambiguous and Whether it Pertains to ANDA Products Created After May 27, 2020.

Under Vermont law, "parties are bound by the plain and express meaning of a contract." *Hoeker v. Dep't of Soc. & Rehab. Servs.*, 765 A.2d 495, 499 (Vt. 2000). "When the plain language of the writing is unambiguous, [the courts] take the words to represent the parties' intent, and the plain meaning of the language governs [the courts']

[6] UCB initially asserted that the Covenant was "a unilateral license[,]" (Doc. 77-10 at 13), and argued that Mylan "failed to carry its burden to prove its breach counterclaim" because it "omit[ted] the contract requirement in arguing breach[.]" *Id.* at 29 (citing *Country Mut. Ins. Co. v. Altisource Online Auction, Inc.*, 2020 WL 4275660, at *5 (D. Vt. July 24, 2020)) (stating that "to sustain a claim for breach of contract, the claimant must demonstrate the existence of an enforceable contract") (internal quotation marks and citation omitted). At the court's October 12, 2023 hearing, however, UCB abandoned this argument and agreed that the Covenant was a contract that Mylan may seek to enforce. (Transcript at 61.) The distinction between a license and a covenant is immaterial, as "a non-exclusive patent license is equivalent to a covenant not to sue[.]" *TransCore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271, 1275 (Fed. Cir. 2009).

interpretation of the contract." *Southwick v. City of Rutland*, 2011 VT 105, ¶ 5, 190 Vt. 324, 327, 30 A.3d 1298, 1300 (internal citation omitted).

"Ambiguity exists where the disputed language will allow more than one reasonable interpretation." *Mueller v. Mueller*, 2012 VT 59, ¶ 22, 192 Vt. 85, 94, 54 A.3d 168, 174 (internal quotation marks and citation omitted). "The question of whether a contract term is ambiguous is a matter of law for the court to decide." *Isbrandtsen v. N. Branch Corp.*, 556 A.2d 81, 83 (Vt. 1988) (citation omitted).

The parties dispute whether the Covenant only applies to Mylan's ANDA Products owned by Mylan as of May 27, 2020, the date referenced in Paragraphs 1 and 3 of the Covenant, or whether it covers future modifications as well. Mylan contends that "May 27, 2020" in Paragraph 1 modifies "possessing" and thus is "neither incorporated into the definition of 'Mylan ANDA' nor in any way definitional[,]" (Doc. 86 at 7), and in Paragraph 3 "does no more than establish the line of demarcation after which the occurrence of those conditions would relieve UCB of its promise not to sue." *Id.* at 8. As a result, it characterizes Paragraph 2 as "a broad promise not to sue untethered to any specific date" that was violated by the filing of this action. *Id.* (emphasis omitted).

UCB counters that the Covenant only applies to ANDA Products that were "described in the Mylan ANDA . . . as of May 27, 2020." (Doc. 77-10 at 18) (internal quotation marks omitted) (alteration in original). It contends any other interpretation would render the Covenant limitless.

Paragraphs 1, 2, and 3 of the Covenant provide in relevant part:

1. This Covenant is conditioned upon Mylan **possessing** all right, title, and interest in and to **[ANDA] No. 209982**, describing a rotigotine transdermal system, including 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours ("**the Mylan ANDA**"), **as of May 27, 2020**.
2. [UCB agrees to covenant not to sue Mylan] for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in **the Mylan ANDA** ("Mylan ANDA Products") infringes any claims of the '979, '980, '591, or '150 patents.

> 3. The Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products **as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020,** provided, however, to the extent that Mylan thereafter – (1) amends, supplements or otherwise alters the Mylan ANDA so as to change any indication(s) sought therein, or (2) modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis[.]

(Doc. 77-49 at 2-3, ¶¶ 1-3) (emphasis supplied). The fifth paragraph ("Paragraph 5") states that: "For the further avoidance of doubt, this Covenant applies only to products made and/or marketed under the Mylan ANDA as defined herein." *Id.* at 3, ¶ 5.

By its plain language, the Covenant refers to Mylan's ANDA that existed as of May 27, 2020. In Paragraph 5, the Covenant seeks to avoid any ambiguity on this point. "[Courts] assume that parties included contract provisions for a reason[.]" *Southwick v. City of Rutland*, 2011 VT 53, ¶ 4, 190 Vt. 106, 109, 35 A.3d 113, 115 (citing *In re West*, 685 A.2d 1099, 1103 (Vt. 1996)) (internal quotation marks omitted). The Covenant thus extends to modifications of the ANDA that existed as of May 27, 2020 only as set forth in Paragraph 3. The plain language of the Covenant yields no other reasonable interpretation. *See Reynolds v. Sterling Coll., Inc.*, 750 A.2d 1020, 1023 (Vt. 2000) ("This court will, where possible, avoid construing the contract in a manner that leads to . . . unreasonable results[.]") (citation omitted). The court thus DENIES Mylan's summary judgment motion on this issue.

D. Whether UCB or Mylan Bears the Burden of Proof.

The parties disagree as to whether Paragraph 3 is a condition subsequent with a burden-shifting requirement or whether the drafter of the Covenant has the burden to prove its meaning. A condition subsequent is "a future event, the happening of which discharges the parties from their otherwise binding agreement." 13 Williston on Contracts § 38:9 (4th ed.) (footnote omitted).

Mylan argues that Paragraph 3 is a condition subsequent "triggered only by changes to the ANDA that 'alter the infringement analysis with respect to' the '979 and '980 Patents." (Doc. 64-12 at 22.) Because this condition subsequent has not been

satisfied, Paragraph 3 "does not apply[.]" *Id.* In support of this argument, Mylan relies on Vermont law,[7] treatises,[8] and state and federal cases[9] that invoke condition subsequent burden shifting. It thus claims that UCB bears the burden of proof.

Mylan further contends that "the infringement analysis" should be construed against UCB as the drafter of Paragraph 3. *See Toys, Inc. v. F.M. Burlington Co.*, 582 A.2d 123, 126 (Vt. 1990) ("[A] doubtful provision in a written instrument is construed against the party responsible for drafting it."). It claims that had UCB wanted to draft a broader version of Paragraph 3, it could have done so, and by excluding broader language, it must be confined to the narrow meaning of any contested terms.[10] Quoting a

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[7] *See McDuffie v. Magoon*, 26 Vt. 518, 522 (1854) ("This condition is clearly in the nature of a . . . condition subsequent, and for the benefit of the makers of the note, and where the burden of proof would lie upon those, for whose benefit the condition was annexed.").

[8] *See* 30 Williston on Contracts § 77:6 (4th ed.) ("[O]ne of the effects of a condition subsequent is that the defendant has the burden of pleading and proving the happening or nonhappening of the conditioning event[.]") (citation omitted); 13 Williston on Contracts § 38:26 (4th ed.) ("[I]f the promise is stated in absolute terms so that it stands complete by itself but is followed by a further statement that the duty will be terminated if a certain contingency occurs—that is, to use the language of procedure if the promise is followed by a proviso—this form of statement will usually operate procedurally to throw the burden both of pleading and of proving the proviso on the defendant[.]") (footnote omitted).

[9] *See, e.g.*, *Prime Finish, LLC v. ITW Deltar IPAC*, 766 F. App'x 183, 186 (6th Cir. 2019) ("Under general principles of contract law, the defendant has the burden of proving conditions subsequent.") (citations omitted); *S'holder Representative Servs. LLC v. Shire US Holdings, Inc.*, 2020 WL 6018738, at *18 (Del. Ch. Oct. 12, 2020) ("[T]he party seeking to avoid a finding of breach bears the burden of proving that the event has occurred and its obligation was extinguished.") (footnote omitted), *aff'd*, 267 A.3d 370 (Del. 2021); *Blandford Land Clearing Corp. v. Nat'l Union Fire Ins. Co. of Pittsburgh*, 698 N.Y.S.2d 237, 241 (N.Y. App. Div. 1999) ("It is defendant's burden, as the party seeking to be relieved from its contractual obligation, to demonstrate that the requisite condition has arisen[.]"); *People v. Bradford,* 124 N.E. 118, 119 (N.Y. 1919) ("[T]he burden will rest upon the defendant, who has peculiar and almost exclusive knowledge of the existence or nonexistence of the facts making the exception, to prove such facts if they do exist.").

[10] *See Grenafege v. Dep't of Emp. Sec.*, 357 A.2d 118, 120 (Vt. 1976) (applying "the time honored precept of 'expressio unius est exclusio alterius[]'"); *Hill v. City of Burlington*, 597 A.2d 792, 795 (Vt. 1991) ("[T]he Policy explicitly provides that . . . employees shall receive compensation for unused vacation leave upon termination. The disability leave sections, which are contiguous, contain no similar language. Because of the omission, we conclude that compensation for sick leave at termination was not contemplated [in the latter]."); *CAML Ghana Ltd. v. Westchester Res. Ltd.*, 2015 WL 405647, at *5 (S.D.N.Y. Jan. 30, 2015) (applying "the

stipulation in a different case in which UCB voluntarily dismissed claims against another drug manufacturer and wherein UCB "carved out the right to sue based on *two* condition[s] subsequent[,]"[11] (Doc. 64-12 at 16) (emphasis in original), Mylan urges the court to find UCB is limited to a specific definition of "the infringement analysis," which Mylan contends can only be found in UCB's 2017 Complaint.

UCB denies that Paragraph 3 is a condition subsequent and contends that even if it is, Mylan has the burden of proof as the movant for summary judgment. It notes the Restatement (Second) of Contracts does not recognize burden shifting because "over forty years ago[]" it eliminated the distinction between a "condition subsequent" and "condition precedent[.]" (Doc. 77-10 at 27) (internal quotation marks omitted).[12] The Vermont Supreme Court has "often relied upon and adopted various provisions within the Restatement (Second) of Contracts[.]" *EverBank v. Marini*, 2015 VT 131, ¶ 25, 200 Vt. 490, 505, 134 A.3d 189, 198.[13] Characterizing "contra proferentem[,]" the practice of construing language against the drafter, as "a rule of last resort[,]" UCB contends it does not apply because it would render the interpretation of Paragraph 3 unreasonable, as it would grant Mylan a license for any future modification of the ANDA it chooses. 11

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familiar principle of expressio unius" and defining it as "the mention of one thing implies the exclusion of the other") (internal quotation marks and italics omitted).

[11] *See UCB, Inc. v. Watson Labs. Inc.*, No. 14-cv-1083-LPS-SRF (D. Del. May 15, 2015), ECF No. 55 at 1 ("This dismissal, however, is made without prejudice to Plaintiffs' ability to assert [the patents] . . . if [d]efendants make a change to the product that is the subject of [the ANDA] and that *change either requires a new or supplemental bioequivalence study* ***or*** alters the infringement analysis[.]") (emphasis supplied).

[12] *See* Restatement (Second) of Contracts § 224, Reporter's Note (1981) ("This Section . . . eliminate[s] the terms 'condition precedent' and 'condition subsequent.' This terminology has long been criticized and has caused confusion when used in an attempt to answer questions related to the burdens of pleading and proof.").

[13] "[T]he Vermont Supreme Court has frequently looked to the Restatements for guidance." *Von Weingarten v. Chester*, 818 F. App'x 110, 112 (2d Cir. 2020), *cert. denied*, 141 S.Ct. 1077 (2021); *see Sullivan v. Saint-Gobain Performance Plastics Corp.*, 431 F. Supp. 3d 448, 454 (D. Vt. 2019) (collecting cases and observing that "[t]he Vermont Supreme Court has frequently followed the Restatement (Second) of Torts"); *Birchwood Land Co. v. Krizan*, 2015 VT 37, ¶ 9, 198 Vt. 420, 425, 115 A.3d 1009, 1012 ("We frequently have adopted provisions of this Restatement [(Third) of Restitution & Unjust Enrichment] where our law is undeveloped.").

Williston on Contracts § 32:12 (4th ed.) (citations and italics omitted).

Paragraph 3 states in relevant part:

> The Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020, provided, however, to the extent that Mylan **thereafter** – (1) **amends, supplements or otherwise alters** the Mylan ANDA so as to change any indication(s) sought therein, or (2) **modifies, adds, removes, or alters** components in the Mylan ANDA Products, or **steps that are used in their manufacture**, **so as to alter the infringement analysis**[.]

(Doc. 77-49 at 2-3, ¶ 3) (emphasis supplied).

Paragraph 3 is a condition subsequent because it is triggered only if Mylan "amends, supplements or otherwise alters" its ANDA or "modifies, adds, removes, or alters" components of its ANDA Products or manufacturing steps so as to alter the infringement analysis. The word "thereafter" is indicative of a condition subsequent. Because the Vermont Supreme Court has not affirmatively rejected condition subsequent burden shifting, which it has previously imposed, *see McDuffie*, 26 Vt. at 522, UCB bears the burden to prove the condition subsequent has occurred. In addition, although Mylan drafted the initial version of the Covenant, it is undisputed that UCB drafted Paragraph 3 with the "the infringement analysis" phrase.

Because UCB is both the drafter of Paragraph 3 and because Paragraph 3 is a condition subsequent, UCB bears the burden of proof. This interpretation places the burden of proving a modification of the ANDA and the ANDA products on the party claiming it has occurred rather than requiring Mylan to prove a negative. The court thus GRANTS Mylan's motion for summary judgment on this issue.

E. Whether the Term "The Infringement Analysis" is Ambiguous.

The parties dispute the meaning of "the infringement analysis" in Paragraph 3:

> The Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020, provided, however, to the extent that Mylan thereafter – (1) amends, supplements or otherwise alters the Mylan ANDA so as to change any indication(s) sought therein, or (2) modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to **alter the infringement analysis** with respect to

> any claim of the '979, '980, '591, or '150 patents – this Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture.

(Doc. 77-49 at 2-3, ¶ 3) (emphasis supplied).

The Covenant neither defines "the infringement analysis," nor dictates a means or method to define it. Mylan asserts that "the" must mean "the infringement analysis" that existed at the time of the Covenant's execution on June 16, 2020, which it contends is set forth in UCB's Complaint in the 2017 Action. It thus asks the court to consider extrinsic evidence in construing the Covenant. *See Beldock v. VWSD, LLC*, 2023 VT 35, ¶ 28, 307 A.3d 209, 222 ("If the plain language of the contract, when reviewed alone, is unclear, [courts] may look to limited extrinsic evidence of circumstances surrounding the making of the agreement to help resolve whether the contract provision is ambiguous.") (internal quotation marks and citation omitted). Mylan directs the court's attention to paragraphs 50 and 57 of UCB's 2017 Complaint, which state:

> 50. Defendants have infringed the '979 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '979 Patent. In the Notice Letter, Mylan has not asserted non-infringement of claims 1-5 or claims 7-18 of the '979 Patent.
>
> . . .
>
> 57. Defendants have infringed the '980 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '980 Patent. In the Notice Letter, [Mylan] has not asserted non-infringement of claim 17 of the '980 Patent.

UCB, Inc. v. Mylan Techs., Inc., No. 2:19-cv-00148, ECF No. 1 at 13, 15 ¶¶ 50, 57.

Although the 2017 Complaint contains UCB's barebones infringement allegations, it does not contain an infringement analysis, nor does it purport to do so. Had the parties agreed that "the infringement analysis" would be defined by reference to UCB's 2017 Complaint, they could have included that reference in the Covenant. Throughout the parties' negotiations, however, there is no evidence this was proposed or that paragraphs 50 and 57 were even referenced, much less discussed. Beyond UCB's 2017 Complaint,

Mylan does not contend that UCB disclosed its infringement analysis to it.

UCB argues that "the infringement analysis" is "black-letter law—not a nebulous matter of subjective knowledge or intent as Mylan suggests[.]" (Doc. 77-10 at 19); *see* 11 Williston on Contracts § 32:4 (4th ed.) ("Technical terms or words of art will be given their technical meaning.") (footnote omitted); Restatement (Second) of Contracts § 202(3)(b) (1981) ("[T]echnical terms and words of art are given their technical meaning when used in a transaction within their technical field."). Asserting "the infringement analysis" is a "technical term of art" used by courts to describe a two-step process articulated by the Federal Circuit, UCB asks the court to define the term as follows:

> An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996) (citation omitted); s*ee also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) ("[T]he essential inquiry [is]: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?"); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003) ("[T]he first step in an infringement analysis is to construe the claims, *i.e.*, to determine the scope and meaning of that which is allegedly infringed. . . . Thereafter, the properly construed claims are compared to the accused product or process to determine whether each of the claim limitations is met, either literally or equivalently.").[14]

In urging the court to adopt the Federal Circuit's definition of "the infringement analysis," UCB asks the court to consider the Covenant's drafting history. As it points

[14] Mylan notes that the Vermont Supreme Court has not adopted the Federal Circuit's definition of "the infringement analysis" as a term of art. It does not cite a patent infringement case decided by the Vermont Supreme Court nor is there a body of case law in Vermont addressing patent infringement. This is unsurprising. "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . . No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents[.]" 28 U.S.C. § 1338(a).

out, Mylan drafted a broader Covenant without Paragraph 3 and with Paragraph 2 including "any amendments and/or supplements" Mylan made to its ANDA.[15] *See* Doc. 77-55. UCB rejected Mylan's proposal and offered Mylan the Covenant on a take-it-or-leave-it basis, informing Mylan that UCB's version "appropriately limits the covenant to the ANDA and generic product of which Plaintiffs are on notice[.]" (Doc. 77-46 at 2.) If Mylan's broad interpretation of the Covenant is accepted, it would recapture what it could not secure in the parties' negotiations.

In addition, UCB points out that its 2017 infringement allegations were revised in the course of the 2017 Action when UCB failed to assert the '979 and '980 Patents per the District of Delaware standard. As a result, UCB abandoned paragraphs 50 and 57 of its 2017 Complaint in the course of the 2017 Action and Mylan was aware of that abandonment. For Mylan to now claim that paragraphs 50 and 57 modify the Covenant and provide a definition of "the infringement analysis" would ignore the law of the case[16] as well as the parties' course of conduct.[17]

Nothing in the drafting history of the Covenant clarifies the parties' intended definition of "the infringement analysis." Both parties urge the court to consider different extrinsic evidence in deciding its meaning. "A provision in a contract is ambiguous . . . to the extent that reasonable people could differ as to its interpretation." *Isbrandtsen*, 556

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[15] UCB claims that under Mylan's proposed Covenant, "***any*** products that Mylan had or ever would propose through an amendment to its ANDA would be fully licensed with respect to the Covenant Patents." (Doc. 77-10 at 12) (emphasis in original). The court agrees that this would be the logical outcome of Mylan's interpretation.

[16] *See Johnson v. Holder*, 564 F.3d 95, 99 (2d Cir. 2009), *cert. denied*, 560 U.S. 919 (2010) ("The law of the case doctrine commands that 'when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case' unless 'cogent and compelling reasons militate otherwise.'") (citing *United States v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir. 2002), *cert. denied sub nom. Donato v. United States*, 539 U.S. 902 (2003)); *Am. Hotel Int'l Grp., Inc. v. OneBeacon Ins. Co.*, 611 F. Supp. 2d 373, 378 (S.D.N.Y. 2009), *aff'd*, 374 F. App'x 71 (2d Cir. 2010) (observing that a trial court decision "remains the law of the case[]" unless reversed on appeal).

[17] *See New Moon Shipping Co. v. MAN B & W Diesel AG*, 121 F.3d 24, 31 (2d Cir. 1997) ("Evidence of a prior course of dealing may establish a party's awareness of and consent to intended contractual terms.").

A.2d at 83 (citation omitted). Although UCB has the better part of the argument, the definition of "the infringement analysis" remains ambiguous. On summary judgment, the court cannot resolve that ambiguity as a matter of law without fact finding regarding the parties' intent and course of conduct. *See Smith v. Lehman*, 689 F.2d 342, 346 (2d Cir. 1982), *cert. denied*, 459 U.S. 1173 (1983) ("[S]ummary judgment is inappropriate where a triable issue of material fact exists concerning the interpretation and possible ambiguity of private agreements entered into between parties[.]") (citing *Heyman v. Com. & Indus. Ins. Co.*, 524 F.2d 1317, 1320 (2d Cir. 1975)). It therefore DENIES Mylan's motion for summary judgment on this issue.

F. Whether "The Infringement Analysis" Has Been Altered.

In addition to their competing definitions of "the infringement analysis," the parties advance competing arguments regarding whether "the infringement analysis" has been altered in light of the amendments to Mylan's ANDA.

UCB contends that there is a genuine dispute of material fact regarding Mylan's changes to its ANDA and their impact on "the infringement analysis" that precludes summary judgment.[18] It urges the court to find that the Covenant only applies to "essentially the same" products which do not include Mylan's "major amendment" to its ANDA Products now under review by the FDA. (Doc. 77-10 at 18.) It further asserts, "Mylan's New Product is manufactured by a different process with different equipment[,]" *id.*, and "had Mylan hypothetically developed a new product that only differed from the Old Product in its color, the infringement analysis for the new product would be the same because none of the licensed claims are directed to the color of the inventive transdermal systems." *Id.* at 20.

Mylan denies that "the infringement analysis" has been altered and asserts that if an "essentially the same" test governs, its modified ANDA products would not give rise

[18] UCB submits the seventy-one-page declaration of Cory Berkland, Ph.D., with a twenty-five-page Appendix addressing whether Mylan modified, added, removed, or altered components of Mylan's ANDA and ANDA Products. Dr. Berkland opined that "the infringement analysis" "involves . . . separate technical inquiries[,]" and does not address it. (Doc. 77-66 at 69-70.) Neither party has therefore provided the court with an infringement analysis.

to an infringement claim because UCB "still contends that the products fall within the claimed ranges based upon the supplemental ANDA[,]" (Doc. 86 at 13), and whether those changes "fall at different points within the claimed range does not alter the 'essentially the same' calculus." *Id.*

Mylan cites *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372 (Fed. Cir. 2008), *cert. denied*, 555 U.S. 1153 (2009), for the proposition that the court may decide this issue as a matter of law. In *Apotex*, the district court decided the infringement issue as a matter of law based on an expert witness declaration. In affirming that conclusion on appeal, the Federal Circuit observed that "[t]hough the court recognized that there are differences in the concentrations of the ingredients in the ANDA–1 and ANDA–2 formulations, it also realized that all of the concentrations are well within the ranges claimed in the '493 patent. . . . [B]oth formulations are encompassed by the claims of the '493 patent. Thus, any difference in composition between the two formulations is merely colorable and the two formulations are 'essentially the same.'" *Apotex*, 531 F.3d at 1380.

Here, any comparison of the ANDA Products cannot be determined on summary judgment without a definition of "the infringement analysis," factfinding, and expert witness testimony regarding whether modifications have occurred and, if so, whether "the infringement analysis" has been altered as a result.

G. Whether Mylan is Entitled to Summary Judgment of Non-Infringement of the '979 and '980 Patents.

Mylan requests summary judgment of non-infringement with regard to the '979 and '980 Patents, arguing that UCB is "foreclose[d,]" (Doc. 64-12 at 19), from bringing this action because the Covenant "immediately terminated [its] ability to maintain suit[.]" *Id.* at 20. UCB counters that this requested remedy is "improper and unavailable based on the grounds presented in Mylan's motion." (Doc. 77-10 at 28.) It asserts that in order to enter such a judgment, the court must "compar[e] the properly construed claims to the device accused of infringing[]" per the two-step process articulated by the Federal Circuit. *Markman*, 52 F.3d at 976.

Until the meaning of "the infringement analysis" is determined, the court cannot

engage in an infringement analysis in accordance with the terms and conditions of the Covenant. The court therefore DENIES WITHOUT PREJUDICE summary judgment with regard to Mylan's claim of non-infringement regarding the '979 and '980 Patents.

CONCLUSION

For the foregoing reasons, Mylan's motion for partial summary judgment is GRANTED IN PART and DENIED IN PART. (Doc. 64.)

SO ORDERED.

Dated at Burlington, in the District of Vermont, this 8th day of March, 2024.

Christina Reiss, District Judge
United States District Court